

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference PCT-12990	FOR FURTHER ACTION	See item 4 below
International application No. PCT/EP2004/014430	International filing date (<i>day/month/year</i>) 17 December 2004 (17.12.2004)	Priority date (<i>day/month/year</i>) 23 December 2003 (23.12.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant DENTSPLY DETREY GMBH		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).
2. This REPORT consists of a total of 6 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Date of issuance of this report 26 June 2006 (26.06.2006)</td> <td style="width: 50%;"></td> </tr> <tr> <td>Authorized officer</td> <td style="text-align: center; vertical-align: middle;">Ellen Moyse</td> </tr> <tr> <td colspan="2">e-mail: pt05@wipo.int</td> </tr> </table>	Date of issuance of this report 26 June 2006 (26.06.2006)		Authorized officer	Ellen Moyse	e-mail: pt05@wipo.int	
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Authorized officer	Ellen Moyse						
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PATENT COOPERATION TREATY

REC'D 23 FEB 2005

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From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2004/014430

International filing date (day/month/year)
17.12.2004

Priority date (day/month/year)
23.12.2003

International Patent Classification (IPC) or both national classification and IPC
A61K6/00, A61K6/087

Applicant
DENTSPLY DE TREY GMBH

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1b/s(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/014430

Box No. 1 Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/014430

**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or
industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	1-12
	No: Claims	
Inventive step (IS)	Yes: Claims	1-12
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-12
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item V.

1 The following documents are referred to in this communication:

D1 : US 2002/143108 A1 (cited in the application)

D2 : US 2003/045604 A1

2 Novelty

D1 discloses dental compositions, e.g. a dental sealant, that has a high adhesion to hard dental tissue and a low volumetric shrinkage. Macromonomers (see D1, claims) can be formed in a two step reaction; the diepoxide is reacted with a disecundary diamine then the obtained prepolymer is reacted with 2,3-epoxypropyl(meth)acrylate (see D1, paragraph [0038]). According to the corresponding Referential Example 5, the intermediate prepolymer is not isolated. D1 further discloses that "it is possible to synthesize the esterified macromonomers without using any catalysts" (see D1, paragraph [0048]). "Fillers of high X-ray absorbence provide radio-opacity values" (see D1, paragraph [0011]). Moreover, D1 does not disclose an intermediate prepolymer suitable for providing an amino terminated prepolymer having a viscosity at 23 °C of less than 100 Pas.

D2 discloses dental root canal filling cones (cf. present application, claim 11) prepared from a radio-opaque filler and a thermoplastic polymer formed by polymerisation of a diepoxide and a primary monoamine and/or secondary diamine (see D2, claims).

Neither D1 nor D2 disclose a dental root canal sealing composition curable in the absence of a polymerisation initiator, which comprises

- (i) an amino terminated prepolymer having a viscosity at 23 °C of less than 100 Pas;
- (ii) a compound capable of undergoing polyaddition with the amino-terminated prepolymer (i);
- (iii) 40 to 85 wt.% of a filler for providing a minimum radiopacity of at least 3 mm / mm Al.

The subject-matter of claims 1-12 is therefore novel [Article 33(2) PCT].

3 Inventive Step

The **problem** to be solved can be regarded as to provide a dental root canal sealing composition having a low viscosity, low cytotoxicity, and low solubility while having excellent mechanical properties such as low shrinkage and flexibility and which do not give rise to handling problems during manufacture and application.

The **solution** is a dental root canal sealing composition curable in the absence of a polymerisation initiator, which comprises

(i) an amino terminated prepolymer having a viscosity at 23 °C of less than 100 Pas; (ii) a compound capable of undergoing polyaddition with the amino-terminated prepolymer (i); (iii) 40 to 85 wt.% of a filler for providing a minimum radiopacity of at least 3 mm / mm Al as disclosed in the subject-matter of claim 1.

Document D1, which is considered to represent the **most relevant state of the art**, discloses dental compositions, e.g. a dental sealant, that has a high adhesion to hard dental tissue and a low volumetric shrinkage. Macromonomers (see D1, claims) can be formed in a two step reaction; the diepoxide is reacted with a dissecondary diamine then the obtained prepolymer is reacted with 2,3-epoxypropyl(meth)acrylate (see D1, paragraph [0038]) from which the subject-matter of claim 1 differs in that D1 does not disclose an intermediate prepolymer suitable for providing an amino terminated prepolymer having a viscosity at 23 °C of less than 100 Pas.

The surprising technical effect of the application of amino terminated prepolymers as one component for a root canal filling material is that because the content of low molecular weight amines is strongly reduced the compatibility with packaging materials as well as biocompatibility are improved, and the polymerisation shrinkage is reduced.

It would not be obvious for a person skilled in the art from the teachings of D1 to arrive at the solution provided for in the subject-matter of claims 1-12 of using such amino terminated prepolymers as one component for a root canal filling material.

Therefore, the subject-matter of claims 1-12 involves an inventive step [Article 33(2) PCT].